

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Certifier

D. Hawkins

Implantation or Injectable Dosage Form New Animal Drugs; Furosemide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of furosemide solution by intramuscular or intravenous injection in horses, cattle, dogs, and cats.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-293 that provides for veterinary prescription use of Furosemide Injection 5% by intramuscular or intravenous administration in horses, cattle, dogs, and cats. Phoenix's Furosemide Injection 5% is approved as a generic copy of Intervet, Inc.'s LASIX Injectable Solution, approved under NADA 34-478. ANADA 200-293 is approved as of December 18, 2001, and the regulations are amended in 21 CFR 522.1010 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food
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and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 522

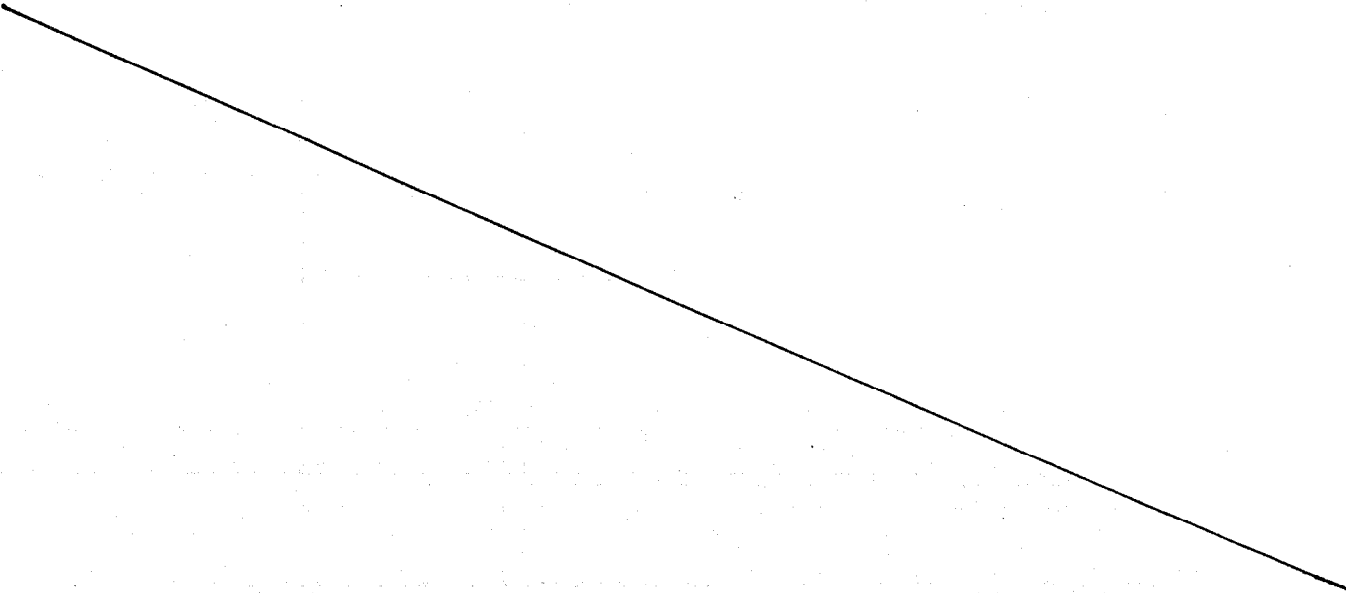
Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

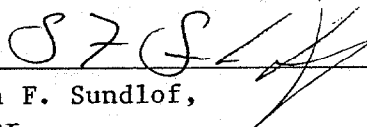


§ 522.1010 [Amended]

2. Section 522.1010 *Furosemide* is amended in paragraph (b)(3) by removing "No. 057926" and by adding in its place "Nos. 057926 and 059130".

Dated: 3/1/02

March 1, 2002.

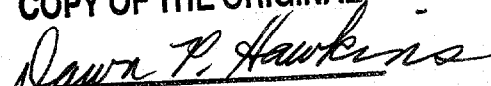


Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins